

Title: **Online Patient Education and Risk Assessment**
 Project OPERA from Cancerbackup

**Putting inherited breast cancer risk information into context using
argumentation theory**

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Abstract

Many people are concerned about their family history of breast cancer, and are anxious about the possibility of developing breast cancer themselves. The majority of these people are likely not to be at significantly increased risk of developing inherited breast cancer. All women are at risk of developing sporadic breast cancer, and this risk increases with age. The UK National Institute of Health and Clinical Excellence has published guidance for the National Health Service on the management of familial breast cancer. That guidance lays down clear criteria for categorising risk level and the appropriate management options. We have developed a user-friendly computer programme named OPERA (Online Patient Education and Risk Assessment) which captures the individuality of the user's situation in a comprehensive way, and then produces personalised information packages, building on the theoretical framework of argumentation developed by Stephen Toulmin (1958). We will test this programme in a series of pilot studies commencing in Spring 2007. This paper describes the progress of this project to date and focuses on the design of the programme.

1. Background

Cancer is an emotive word within the general population, but it causes even more anxiety amongst individuals with previous experience of the diagnosis of cancer in other members of the family. Breast cancer has a particularly high political and media profile, and there appears to be a real, but probably exaggerated fear, of developing breast cancer in family members of women who have already developed the disease.

Several sets of guidelines have been published which outline the approximate risk to relatives of developing inherited breast cancer, depending on the strength of their family history of breast and ovarian cancer. All these guidelines, which differ on minor details rather than on any issues of important substance, concentrate on informing those individuals considered to be at high, or significantly increased risk. These individuals may be offered access to genetic testing or to programmes of more intensive screening to identify early disease.

However, individuals who have what is considered to be a significant family history of breast cancer only constitute a small minority of all those who have some family history of breast cancer. The majority of women who have a relative with breast cancer are not at significantly increased risk of developing inherited breast cancer themselves. Their risk of developing non-genetic or sporadic breast cancer increases with age and other lifestyle factors in exactly the same fashion as women who have no family history of disease.

This situation therefore represents a real challenge to healthcare professionals with expertise in the communication of clinical information to non-expert audiences. On one side, the important clinical message is that the risk of developing breast cancer because of the family history of disease is not very high compared to those rare individuals with a

very strong family history. On the other side, the important message is that ALL women are at risk of developing breast cancer, the biggest known risk factor of which is increasing age.

In Europe the lifetime risk of developing breast cancer is around 9-11%, making breast cancer the most common female cancer. In the UK this is considered such a significant problem in public health terms, that the National Health Service (NHS) offers regular breast screening to all women once they reach the age of 50. This programme is one of only two fully funded adult cancer screening programmes offered from the public purse. Considerable resources have been devoted to establishing and running this programme, including extensive media campaigning to encourage as many women as possible from all backgrounds to attend for free breast screening

2. A difficult problem

The aim of giving accurate information is to reduce anxiety, which is perceived by an external observer to be inappropriate and therefore in some way unnecessary. Information, which reduces appropriate anxiety, would be considered misleading. The whole issue of appropriate anxiety, regarding the risk of breast cancer, is driven, at least in part, by the provision of a state sponsored mammographic screening programme from the age of 50, with uptake being considered one of the important quality indicators of the programme.

One important goal of a programme such as Cancerbackup's OPERA, which aims to give individuals information about their risk of developing inherited breast cancer, must be to reduce the anxiety of those who do not have a significant family history of disease down

to the level of those without any family history. However, such women should still be concerned enough about every woman's risk of developing breast cancer to join the National Screening Programme when they are 50.

An important distinguishing factor between inherited and sporadic breast cancer is the average age of onset. In general, inherited breast cancer develops at a younger age than sporadic breast cancer. Specifically, a carrier of the BRCA1 gene mutation has a 50% chance of developing breast cancer before the age of 50; in the normal population the risk of developing breast cancer below 50 years of age is 1%. The provision of state sponsored breast screening in the UK from the age of 50 may be a convenient, although artificial, discriminator which helps convey the important messages.

The real challenge which OPERA faces is in informing those who are at low risk of developing inherited breast cancer; balancing the good news of low inherited risk with the ever present risk of sporadic breast cancer which every woman faces.

3. The ingredients available

The National Institute for Health and Clinical Excellence (NICE) examines all the available evidence, and offers guidance to the National Health Service in the UK. It has no powers of implementation, but the guidance produced on those subjects, which have been referred to NICE, is considered authoritative. NICE produced guidance on the Management of Familial Breast Cancer in 2004¹, which sets out criteria, based on strength of family history, for triaging individuals into three different risk groups: high, moderate and low. Different management options are available within the National

¹ Familial breast cancer: the classification and care of women at risk of familial breast cancer in primary, secondary and tertiary care. (Clinical Guideline 041, partially updated in October 2006) www.nice.org.uk

Health Service for each group, although there is general agreement that the options available to the low risk group are very limited. As noted above, most guidelines concentrate on informing the high and moderate risk groups of the available options, but at least the NICE guidance provides authoritative, and generally accepted, criteria for determining the low risk group.

Cancerbackup is the leading provider of information for cancer patients, their relatives and carers in the UK. In collaboration with University College London, Cancerbackup secured a grant from the UK Department of Health to fund a project on the provision of patient information about cancer genetics. The first part of this project involved the development of a booklet on cancer genetics for families who would be offered genetic testing within the NHS. This booklet won an award for clarity from the British Medical Association. Subsequent work involved the production of five different leaflets for patients with a family history of different cancers, which would not be considered strong enough to warrant the offer of genetic testing within the NHS; the so-called low risk group, although it is widely accepted that this is a misleading label for that group. These leaflets have been immensely popular with over 100,000 already distributed within the UK.

University College London is the original college of the University of London, and was founded in 1826, as the third university in England after Oxford and Cambridge. UCL has a long and distinguished history of research into human genetics, beginning with Sir Francis Galton, a nephew of Charles Darwin. The Galton laboratory, founded in his memory was considered to be the best place in the world to study human genetics for most of the 20th century. The Institute of Communication and Health of the University of

Lugano is one of only three healthcare communication laboratories in Europe. In partnership with the Technology Enhanced Communication Laboratory of the same University, researchers have become expert in the application of advanced IT solutions to facilitate communication within healthcare.

4. Project OPERA; Online Patient Education and Risk Assessment

Cancerbackup's OPERA for inherited breast cancer is a user friendly computer programme which invites the user to enter details of their personal history of breast and/or ovarian cancer and the details of their family history of breast and/or ovarian cancer. The programme also gathers some information on age, sex, ethnicity and history of other cancers that are relatively rare but may be important in assessing an individual's risk of developing inherited breast cancer. The user is led through the process by a series of clear unambiguous questions. Once the information has been gathered by the programme it is summarised in the form of a simple table for the user to verify.

Rules for risk assessment and clinical management, based on the Clinical Guideline on Familial Breast Cancer (Clinical Guideline 041, partially updated in October 2006, www.nice.org.uk) published by the National Institute for Health and Clinical Excellence (NICE), are applied to the information given by the user. A personalised information package is then presented to the user explaining the risk assessment process, and the various management options that would be expected to be available to the user. The user is also offered access to information which is not directly relevant to them, but may interest them.

Users are warned that alterations in their personal or family history may significantly alter the information which is pertinent to them (they are advised to repeat the process if this is the case), and they are invited to send their information anonymously to Cancerbackup to be used to compile statistics on user profile and frequency of use.

The final section of the information package contains a list of suggestions as to what the user might do next and where to go for further information. This is regarded as a particularly important section, the primary aim of the OPERA being not to cause unfounded anxiety, rather to inform and support the user. Furthermore, it is not intended that the use of OPERA should bypass a clinical consultation. The intention is to increase the user's understanding of the risk assessment process in the NHS, thereby empowering the user to access clinical services appropriately, and to complement those services.

Structuring the information package so that it is considered by the user to be a useful and trustworthy source of information, was one of the challenges facing the team of the Institute of Communication and Health of the University of Lugano. As discussed earlier in this paper, the challenge of contextualising inherited breast cancer risk in the low or near-population risk group was particularly great.

5. Theoretical Approach: Explanations as Arguments

In the last few years, due an increased availability of genetic tests and a growth in genetic counselling, the study of risk communication in the field has produced several important contributions [1] [2]. Yet, although the issue of delivering information about cancer genetics according to people's level of risk has arisen in the literature [3] [4] [5] and,

also, there are several studies on online genetics risk communication [6] [7] [8] [9], the issue does not seem to have been addressed in the perspective of our study.

We acknowledge that there are various risk assessment tools already available online. In an attempt to understand the communication strategy adopted by existing risk assessments we made a benchmarking analysis of these instruments, aimed at highlighting the distinctive features of the applications from the point of view of the navigation/interaction and the nature of the contents delivered. There we noted that, traditionally, human-system transactions in this sector result in outputs which do not explain the reasons for the outputs themselves. Knowledge-based systems do not normally justify their conclusions to its users. To give some examples:

Using a risk assessment for calculating the risk of breast cancer (the real name of the instrument is left out for reasons of privacy) the user is invited to answer a set of questions. By then clicking on the box titled 'calculate risk', users receive answers of the following type:

Your chance of being diagnosed with breast cancer is estimated to be 29.8% within lifetime (to age 90).

Apart from the presence in this type of messages of percentages, whose usage in risk assessment is not without complication [10], the important thing to note is that there is no additional content to explain what this percentage means and why it is so.

Again, another risk assessment tool for genetic breast cancer generates messages of the following type:

Compared to a typical woman of your age, your risk is average.

Here, again, there is no indication of how the answers given by the user point to the risk classified as average.

Existing online tools seem to produce answers from authority, where the main claims are left unsupported. This lack of support seems to be a critical limitation in the above way of delivering risk assessment tests, insofar as users are not given enough information for reflecting on the reasons behind their risk levels.

Within this context, the communication strategy of OPERA was designed using argumentation theory. This theory offers a mechanism for supporting the main claims or, technically speaking, ‘standpoints’ (van Eemeren) about the information provided and options for subsequent action by the user. At the same time, using argumentation in delivering health related information may facilitate understanding, helping the user to contextualise it in the framework of their individual situation. This may enhance the acceptability of the information to the user.

The classical explanation of the term argumentation is that argumentation is a process of giving reasons for taking certain standpoints on issues which are intrinsically problematic and which allow different solutions [11] [12] [13]. Two of the authors have shown elsewhere that the process of argumentation has consequences on the way people process health information [14] [15]. Argumentation offers information to be used as points of reference for structuring decisions. According to the theory of argumentation, it:

- adds motivators, in Searle’s terms [16], to the internal reasons (factual information and intentional) and to other propositionally structured entities such as needs, commitments and requirements ,and

- stimulates the appraisal of the relative weights of the whole set of motivators in arriving at a decision.

Clearly, the ultimate outcome of the interaction must always take into consideration the gap between the deliberative process and the decision itself, as well as between the intention-in-action and the actual carrying out of the activity to its completion (Searle 2001). Individual decisions in terms of behaviour are ultimately affected by a series of factors that, as social scientists know well, is very difficult to determine. Argumentation is a useful concept to help healthcare workers present information in a manner which engenders confidence and acceptance in their listeners, because the listener is presented with the motivation behind the information. To use a recent key-concept in health research, argumentation has an impact on people's health literacy [17] by displaying a variety of possible actions and enhancing choice among these actions. Translating this into human-machine interaction, users' understanding and acceptance of the risk assessment information delivered by OPERA will depend on, and may be enhanced by, the system explaining its reasoning and thereby justifying its conclusions [18].

In light of this background, OPERA implements an explanation framework that justifies the information given. The central component is an explanation strategy that decides what information justifies a claim in the expected direction. The main design criteria for OPERA's information packages are as follows:

- 1) the NICE Guideline for the management of familial breast cancer¹ forms the evidence base for the entire programme.

- 2) The claim indicating the level of risk, and the available management options, should make transparent the rules that lead to that claim being made. The programme should also offer broader supporting material (e.g. reference to medical literature, specific articles and, ultimately the guidelines) and sources of personal support (e.g. details of helplines or places where the user may go for further help or explanation).
- 3) The explanation should include a rebuttal, which aims to ensure that the user does not form an incorrect inference from the claim made .
- 4) The explanation should contain an indication of the confidence with which the claim is made. In dealing with inherited cancer risk, in particular, it has to be clear that should the personal or family history of the user change, s/he would have to repeat the assessment.

The structure and design of OPERA'S information packages are based on the scheme that Stephen Toulmin utilised in his theory of reasoning in 1958 [19] (Figure 1). Indeed, we note that Toulmin's structure allows an identification of all the elements which are relevant for implementing the proposed model of risk communication. Central to his theory is a six-element structure that can be use to generate the explanations. This structure reads as follows:

1. *Data*: the evidence, facts, background data and information we use to make the claim;

2. *Warrant*: the component of the argument that establishes the logical connection between the data and the claim, acting as the reasoning process used by the speaker to arrive at the claim;
3. *Backing*: the grounding material that supports the warrant in the argument;
4. *Rebuttal*: an exception or dissociation of aspects for which the claim presented is not valid;
5. *Qualifier*: the verbalization of the relative strength of an argument;
6. *Claim*: the assertion or conclusion put forward for general acceptance.

Figure 1, here

The phenomenon of risk perception resistance is known in the literature [20]. This aspect is particularly critical when users have reasons for using OPERA which require answers beyond the simple explanation ‘You do not appear to have any significant personal or family history (according to the national guidelines for risk assessment)’.

In the next paragraph we will illustrate how the theoretical design features of the explanations delivered by OPERA are to be implemented.

6. OPERA’s Information Packages

6.1 From Theory to Practice (and Back Again)

To give empirical value to an important aspect of our approach, we made a content analysis of letters written by genetic counsellors to their patients to inform the construction of the personalised information packages within OPERA. These letters are

tailored documents summarizing services and information provided to the patient which the genetic counsellor writes after a face to face consultation. In the analysis, we noted that many counsellors instinctively support any statements they make with an explanation, perhaps subconsciously following the argumentation theory. This is demonstrated in the extract of one of the letters we analysed, which is shown in figure 2.

Figure 2, here

Here we can see that the counsellor states that the cancer was probably sporadic (not due to an inherited genetic mutation) on the basis of the data given by the patient (namely, the daughter-in-law who is not a blood relative of the patient and the aunt who developed breast cancer in her 60s), backing up this statement by quoting some broad pointers as specified by clinical guidelines (points 1, 2 and 3 in the letter).

6.2 Applying the general theory to the construction of the personalised information packages

Figure 3 outlines the specific application of Toulmin's theory to the information packages within OPERA. The initial claim is represented by an indication of the risk level, with the secondary claim being represented by a description of the options available. Relevant medical literature and scientifically authoritative sources (Warrant) and reference to guideline knowledge base (Backing) provide the basis for the claims made. If data is missing, or incorrect (Rebuttal), then the claim is rendered invalid. The claims hold for

the specific context of inherited breast cancer, as outlined within the guidance provided by NICE (Qualifier).

Figure 3, here

The above scheme results in the information package for OPERA users composed of 5 parts, namely:

1. **Your present situation:** an indication of the risk level (*e.g. Your answers suggest that there is a slightly increased chance that there is a faulty breast cancer gene in your family*);
2. **Explanation:** the justification of ‘your present situation’ on the basis of the data inserted and national guidelines;
3. **What next?** a description of possible options which may be offered;
4. **What might change your current situation**
5. **How confident can you be?** stating that the information package is based on the NICE Guideline. Other sources of support are also offered.

As stated earlier, users who, based on their answers to the questions, do not appear to be at increased risk, are asked a question to try to elucidate their reason(s) for using OPERA. To help formulate this question, a content analysis of media articles published in British newspapers in the last 12 months was performed in order ascertain factors which

influence people's understanding and worries about breast cancer in the family. Three main categories of influence came to light:

- *Influence from healthcare workers;*
- *Influence from relatives and friends;*
- *Influence from the media.*

This question, which seeks to discover the user's motivation for accessing the tool, will no doubt require refinement on the basis of results from the three pilot studies of OPERA (using volunteers) to be conducted over the next 12 months.

7. Conclusion

We have developed a user friendly programme to present a personalised information package to individuals who are concerned about inherited breast cancer risk. This programme gathers personal medical data and information about relatives who have developed cancer, and then produces the personalised information based on guidance produced for the National Health Service by the National Institute for Health and Clinical Excellence. In designing OPERA, much attention has been paid to creating a programme that seeks to capture the individuality of the user's situation in a comprehensive way.

This project investigates the possibility of building a more human-like automated system by relying on insights from humanistic disciplines.

The intention is to test this framework in 3 pilot studies (respectively with samples of 20, 100 and 300 users) over the next 12 months. This will enable us to understand the actual impact on the user of information presented in this way.

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